DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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JUL 13 2000

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

VIA FEDERAL EXPRESS

WARNING LETTER

Mr. Eduard Samson
President & Owner
Cirugia Peruana S.A.C.
Av. Colonial 1255
Aptdo. 3624
Lima 1, Peru

Dear Mr. Samson:

During an inspection of your firm located in Lima 1, Peru on April 17 through 19, 2000, our investigator determined that your firm manufactures sterile absorbable and non-absorbable stainless steel sutures. These are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as listed below. Your response, dated May 16, 2000, to the investigator's findings was also reviewed. Comments on your response follow each observation.

1. Failure to establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meet the requirements of this part, as required by 21 CFR 820.5. For example, a quality system was not established or documented.

   Your response is not adequate. The response acknowledged that there are FDA 483 observations but did not address corrective action for the observations. You need to establish and maintain a quality system that is appropriate for the manufacturing of sterile absorbable and non-absorbable stainless steel sutures.

2. Failure to establish its policy and objectives for, and commitment to, quality, as required by 21 820.20(a). For example, a quality policy with objectives have not been established.

Your response is not adequate. The response acknowledged that there are FDA 483 observations but did not address corrective action for the observations. You need to establish a quality policy.

3. Failure to establish a quality plan which defines the quality practices, resources and activities relevant to devices that are designed and manufactured, as required by 21 CFR 820.20(d). For example, quality plans with objectives have not been established.

   Your response is not adequate. The response acknowledged that there are FDA 483 observations but did not address corrective action for the observations. You need to establish a quality plan to define the quality practices, resources and activities relevant to the devices that your firm designs and manufacture.

4. Failure to establish procedures for management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements for this part and the manufacturer's established quality policy and objectives, as required by 21 CFR 820.20(c). For example, procedures for management review and audit of the quality system have not been established.

   Your response is not adequate. The response acknowledged that there are FDA 483 observations but did not address corrective action for the observations. You need to establish procedures for management with executive responsibility to review the suitability and effectiveness of the quality system.

5. Failure to establish procedures where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance, as required by 21 CFR 820.75(a). For example, the ethylene oxide (EO) sterilization and blister packaging equipment processes were not validated.

   Your response is not adequate. The response acknowledged that there are FDA 483 observations but did not address corrective action for the observations. You need to establish validation procedures for the ethylene oxide (EO) sterilization and blister packaging equipment processes.

6. Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a). For example, procedures for corrective and preventive actions have not been established.

   Your response is not adequate. The response acknowledged that there are FDA 483 observations but did not address corrective action for the observations. You need to establish and maintain procedures for implementing corrective and preventive action for nonconforming products.

7. Failure to establish and maintain procedures for investigating the cause of noncomformities relating to product, processes, and the quality system, as required by 21 CFR 820.100(a)(2). For example, procedures for failure investigations have not been established.

   Your response is not adequate. The response acknowledged that there are FDA 483 observations but did not address corrective action for the observations. You need to establish and maintain procedures for failure investigations of nonconforming products.

8. Failure to maintain device master records (DMR's), as required by 21 CFR 820.181. For example, there are no DMR's for the different types of sutures.

   Your response is not adequate. The response acknowledged that there are FDA 483 observations but did not address corrective action for the observations. You need to maintain device master records (DMR's) for the different types of sutures that your firm manufactures.

9. Failure to establish calibration procedures to include equipment identification, calibration dates, the individual performing each calibration, and the next calibration date, as required by 21 CFR 820.72(b)(2). For example, there are no records to ensure calibration of equipment is routinely done.

   Your response is not adequate. The response acknowledged that there are FDA 483 observations but did not address corrective action for the observations. You need to establish procedures to ensure that the equipment used during the manufacturing process is routinely calibrated.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the closeout of the inspection may be

symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Given the serious nature of these violations of the Act, all devices manufactured by Cirugia Peruana S.A.C., Av. Colonial 1255, Aptdo. 3624, Lima 1, Peru may be detained without physical examination upon entry into the United States (U.S.) until these violations are corrected.

In order to remove the devices from detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review where we have judged your response as less than adequate. After we notify you that the response is adequate, a re-inspection will be required to verify that your corrective actions have been implemented. As soon as the inspection has taken place, and the implementation of your corrections has been verified, your products may resume entry into this country.

Please notify this office in writing of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter.

If documentation is not in English, please provide an English translation to facilitate our review.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement I, General Surgery Devices Branch, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Wayne Q. Miller.

Sincerely yours,

Steven M. Niedelman
Acting Director
Office of Compliance
Center for Devices and
Radiological Health